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FORM PTO-1390(Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: **PG3619USW**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR): **09/914999**

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB00/00919	**10 March 2000**	**10 March 1999**

TITLE OF INVENTION
Dose Protector for Inhalation Device

APPLICANT(S) FOR DO/EO/US
Michael Birsha DAVIES

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U S C 371(f)) The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau)
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U S C. 371(c)(2))
   a ☐ is attached hereto.
   b ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U S C 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau)
   b ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U S C 371 (c)(4))
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5))
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409)
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3 28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1 825
20. ☐ A second copy of the published international application under 35 U S C 154(d)(4)
21. ☐ A second copy of the English language translation of the international application under 35 U.S C. 154(d)(4)
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Copy of PCT Request
Copy of PCT Cover Sheet

Express Mail Label
EL395894914US

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/914999	PCT/GB00/00919	PG3619USW

24. The following fees are submitted	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1 445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1000.00**		
☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$860.00**		
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$710.00**		
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$690.00**		
☐ International preliminary examination fee (37 CFR 1 482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$860.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$0.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	30 - 20 =	10	x $18.00	**$180.00**	
Independent claims	2 - 3 =	0	x $80.00	**$0.00**	
Multiple Dependent Claims **(check if applicable)** .			☐	**$0.00**	
TOTAL OF ABOVE CALCULATIONS =				**$1,040.00**	
☐ Applicant claims small entity status. (See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				**$0.00**	
SUBTOTAL =				**$1,040.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1 492 (f)) +				**$0.00**	
TOTAL NATIONAL FEE =				**$1,040.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)) The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐				**$0.00**	
TOTAL FEES ENCLOSED =				**$1,040.00**	
				Amount to be: refunded	$
				charged	$

a. ☐ A check in the amount of _____ to cover the above fees is enclosed

b. ☒ Please charge my Deposit Account No. **07-1392** in the amount of **$1,040.00** to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **07-1392** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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REGISTRATION NUMBER

September 5, 2001
DATE

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): **Michael Birsha DAVIES**	Docket No. **PG3619USW**

Serial No.	Filing Date	Examiner	Group Art Unit
371 of PCT/GB00/00919			

Invention: **Dose Protector for Inhalation Device**

I hereby certify that this **Patent application under 35 USC 371 with corresponding papers**
(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231-0001 on **September 6, 2001**
(Date)

Elaine Martens
(Typed or Printed Name of Person Mailing Correspondence)

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(Signature of Person Mailing Correspondence)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael Birsha DAVIES
International Application No.: PCT/GB00/00919
International Filing Date: 10 March 2000
Title: Dose Protector for Inhalation Device

Commissioner of Patents
Washington, D.C. 20231

FIRST PRELIMINARY AMENDMENT

Dear Sir:

The above identified application is being transmitted herewith for entry in the US National Phase under Chapter II of the PCT for the purpose of adding the priority information. Also please insert the following amendments in accordance with 37 CFR 1.121.

In the Abstract:

Please substitute the attached Abstract, which has been placed on a separate sheet of paper according to US practice, as required under 37 CFR 1.72(b)

In the Specification:

Page 1, delete the Title and replace it with "Dose Protector for Inhalation Device"

On the first line of the specification, after the Title, please add:

--This application is filed pursuant to 35 U.S.C. §371 as a United States National Phase Application of International Application No. **PCT/GB00/00919** filed **10 March 2000**, which claims priority from **GB9905538.6 filed 10 March 1999** in the United Kingdom--

In the Claims:

Claim 3. (Amended) A dose protector as claimed in claim 1 wherein the airflow through and/or pressure drop across the airway is caused by patient inhalation.

Claim 4. (Amended) A dose protector as claimed in claim 1 wherein the said covering means senses airflow through and/or pressure across drop the airway and responds thereto.

Claim 6. (Amended) A dose protector as claimed in claim 1 wherein the covering means responds by covering the dose more effectively when the airflow through and/or pressure drop across the airway is in a second direction.

Claim 8. (Amended) A dose protector as claimed in claim 1 where the covering means comprises one or more poppet valves, diaphragm valves, rotary valves, reciprocating valves, sealing flaps or a combination thereof.

Claim 9. (Amended) A dose protector as claimed in any claim 1 wherein the dose is metered by volume of medicament or surface area.

Claim 12. (Amended) A dose protector as claimed in claim 1 wherein the dose or container retaining the dose has a surrounding rim.

Claim 15. (Amended) A dose protector as claimed in claim 13 additionally comprising a closure mechanism wherein the at least one sealing flap is held in contact with the pocket by a closure means which prevents the contact between the at least one sealing flap and the pocket being broken by airflow through the airway in any direction.

Claim 17. (Amended) A dose protector as claimed in claim 13 wherein the said sealing flap vibrates in the airflow once the contact with the pocket is broken.

Claim 18. (Amended) A dose protector as claimed in claim 13 wherein the sealing flap is made of thermoset rubber.

Claim 19. (Amended) A dose protector as claimed in claim 13 wherein the sealing flap is of equivalent or slightly reduced width relative to the distance between the inside walls of the housing at the base of the walls of the housing where the sealing flap is in contact with the pocket.

Claim 21. (Amended) A dose protector as claimed in claim 1 wherein the said covering means is spaced away from the dose or container retaining a dose to

coincide with the airflow through and/or pressure drop across in the first direction once the contact with the dose or container retaining the dose is broken.

Claim 22. (Amended) A dose protector as claimed in claim 1 wherein the covering means vibrates in the airflow through and/or pressure drop across the airway in the first direction.

Claim 23. (Amended) A dose container as claimed in claim 1 wherein the housing contains a valve flap such that when the airflow is in a second opposite direction, the airflow exits the housing by means of the valve flap.

Claim 24. (Amended) A dose protector as claimed in claim 1 wherein the said covering means protects the dose from the patient exhaling into the device, moisture contamination, particulate contamination and loss of the dose or a combination thereof.

Claim 25. (Amended) A dose protector as claimed in claim 1 additionally comprising a fixed seal.

Claim 26. (Amended) A dose protector as claimed in claim 1, in combination with a dose of medicament.

Claim 27. (Amended) An inhaler comprising a body, a mouthpiece, and a dose protector as claimed claim 1.

Claim 29. (Amended) An inhaler as claimed in claim 26 in combination with at least one dose of a medicament.

Claim 30. (Amended) Use of an inhaler as claimed in claim 27 for the administration of medicament.

REMARKS/ ARGUMENTS

This application is an U.S. National Phase application of PCT/GB00/00919 filed via the Patent Cooperation Treaty under 37 CFR 371. Claims 1-30 are currently pending.

The Title has been amended herein to more appropriately describe the subject matter disclosed in the specification in accordance with United States practice. Further, Claims 3, 4, 6, 8, 9, 12, 17-19, 21-27, 29 and 30 have been amended to eliminate multiple dependencies adapting the PCT application to US practice and reducing prosecution fees.

Attached hereto is a marked version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

James P. Riek
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

The Title has been changed as follows: ~~"Improvements Relating To an Inhalation Device"~~ to "Dose Protector for Inhalation Device"

In the Claims

Claims 3, 4, 6, 8, 9, 12, 17-19, 21-27, 29 and 30 have been amended as follows:

Claim 3. (Amended) A dose protector as claimed in claim 1 ~~or claim 2~~ wherein the airflow through and/or pressure drop across the airway is caused by patient inhalation.

Claim 4. (Amended) A dose protector as claimed in claim 1 ~~claims 1 to 3~~ wherein the said covering means senses airflow through and/or pressure across drop the airway and responds thereto.

Claim 6. (Amended) A dose protector as claimed in ~~any preceding~~ claim 1 wherein the covering means responds by covering the dose more effectively when the airflow through and/or pressure drop across the airway is in a second direction.

Claim 8. (Amended) A dose protector as claimed in claim 1 ~~claims 1 to 7~~ where the covering means comprises one or more poppet valves, diaphragm valves, rotary valves, reciprocating valves, sealing flaps or a combination thereof.

Claim 9. (Amended) A dose protector as claimed in any claim 1 ~~one of claims 1 to 8~~ wherein the dose is metered by volume of medicament or surface area.

Claim 12. (Amended) A dose protector as claimed in claim 1 ~~any preceding claim~~ wherein the dose or container retaining the dose has a surrounding rim.

Claim 15. (Amended) A dose protector as claimed in claim 13 ~~or claim 14~~ additionally comprising a closure mechanism wherein the at least one sealing flap is held in contact with the pocket by a closure means which prevents the contact between the

at least one sealing flap and the pocket being broken by airflow through the airway in any direction.

Claim 17. (Amended) A dose protector as claimed in claim 13 ~~any one of claims 13 to 16~~ wherein the said sealing flap vibrates in the airflow once the contact with the pocket is broken.

Claim 18. (Amended) A dose protector as claimed in claim 13 ~~any one of claims 13 to 17~~ wherein the sealing flap is made of thermoset rubber.

Claim 19. (Amended) A dose protector as claimed in claim 13 ~~any one of claims 13 to 18~~ wherein the sealing flap is of equivalent or slightly reduced width relative to the distance between the inside walls of the housing at the base of the walls of the housing where the sealing flap is in contact with the pocket.

Claim 21. (Amended) A dose protector as claimed in claim 1 ~~claims 1 to 12~~ wherein the said covering means is spaced away from the dose or container retaining a dose to coincide with the airflow through and/or pressure drop across in the first direction once the contact with the dose or container retaining the dose is broken.

Claim 22. (Amended) A dose protector as claimed in claim 1 ~~any one of claims 1 to 21~~ wherein the covering means vibrates in the airflow through and/or pressure drop across the airway in the first direction.

Claim 23. (Amended) A dose container as claimed in claim 1 ~~claims 1 to 22~~ wherein the housing contains a valve flap such that when the airflow is in a second opposite direction, the airflow exits the housing by means of the valve flap.

Claim 24. (Amended) A dose protector as claimed in ~~any preceding~~ claim 1 wherein the said covering means protects the dose from the patient exhaling into the device, moisture contamination, particulate contamination and loss of the dose or a combination thereof.

Claim 25. (Amended) A dose protector as claimed in ~~any preceding~~ claim 1 additionally comprising a fixed seal.

Claim 26. (Amended) A dose protector as claimed in claim 1 ~~any one of claims 1 to 25~~, in combination with a dose of medicament.

Claim 27. (Amended) An inhaler comprising a body, a mouthpiece, and a dose protector as claimed ~~in any preceding~~ claim 1.

Claim 29. (Amended) An inhaler as claimed in claim 26 ~~or claim 27~~ in combination with at least one dose of a medicament.

Claim 30. (Amended) Use of an inhaler as claimed in claim 27 ~~any one of claims 27 to 29~~ for the administration of medicament.

DOSE PROTECTOR FOR INHALATION DEVICE

Abstract

A dose protector for use in an inhaler comprising a housing (40) defining an airway; a dose of medicament optionally retained in a dose container (20, 30); and covering means (10) for said dose wherein covering means (10) for the dose only opens in response to airflow though and/or pressure drop across the airway in a in a first direction but not in a second, opposite direction.

Improvements Relating To An Inhalation Device

The present invention relates to a device for the protection of a dose of medicament in an inhalation device for use in the administration of medicament to a patient.

The use of inhalation devices in the administration of medicaments, for example in bronchodilation therapy, is well known. Such devices generally comprise a body or housing within which a medicament container is located. A mouthpiece (or nozzle) is typically provided, wherein 'in use' the mouthpiece communicates with the medicament container to allow passage of medicament from the source to the mouthpiece and thence, to the patient.

In a typical dispensing operation the body of the device is held by the patient and the mouthpiece (or nozzle) of the inhalation device is placed in the mouth (or nose) of the patient. The patient inhales, thereby causing transfer of medicament from the medicament container to the interior of the body of the patient.

Many inhalers are known where the medicament is stored in a pocket, which is sealed for the purpose of preventing any loss of medicament during transportation or in order to reduce the moisture contamination of the medicament during the life of the inhaler. Examples of such are disclosed in EP0211595, where the medicament is loaded directly into a blister pack comprising a sheet; which may be laminated, of foil or plastics material which acts as a carrier and which is provided with a number of breakable or openable containers called "blisters" incorporating a sheet secured on a first sheet forming a cover or lid. A plunger can then be carried by the lid and arranged to

penetrate a container when the lid is moved to its open position. A device disclosed in WO97/25086, comprises a spider having pads, resiliently urged into contact with the pockets of the device, said pads being raised away from the pocket by rotation of the spider prior to the use of the inhaler.

A device disclosed in US5,860,419 comprises medicament metered into blisters. The foil seal is peeled back to expose the medicament such that as the blister approaches the airway it is exposed for use.

However, the problem with these inhalers is that once they are prepared for use, i.e. once the seal of the pocket or "blister" is broken or removed, the medicament is exposed to the atmosphere inside the inhaler. The medicament could be dislodged from the pocket if the inhaler is shaken, dropped, or the user exhales into the device.

Similar problems exist with reservoir inhalers where the dose is metered in use. Examples of reservoir devices include that known as Turbohaler as described in EP0237507 and EP0069715, and the device described in WO97/20589.

Thus according to the present invention there is provided a dose protector for use in an inhaler comprising a housing defining an airway; a dose of medicament optionally retained in a dose container; and covering means for said dose wherein covering means for the dose only opens in response to airflow though and/or pressure drop across the airway in a first direction but not in a second, opposite direction.

Amongst the advantages of the present invention in one or more of its embodiments are included that it provides a reduction in moisture contamination of the medicament, particulate contamination of the dose, loss of the dose if the

device is inverted, dropped or shaken, until the point of inhalation by the patient. Air exhaled into the device by the patient does not come into contact with the medicament, thereby reducing contamination of the medicament by moisture or particulates, or the medicament being dislodged from the pocket by the patient exhaling into the device.

It follows that the advantages of the present invention include that it also ensures that the full dose metered is available to the patient in that part of the dose is prevented from being lost such as, for example being lost within the device, if the complete dose is not taken in the first inhalation, as may be the case with the elderly and children.

Preferably the covering means is only open in the presence of airflow through and/or pressure drop across the airway in a first direction after which it returns to its resting position.

The airflow through and/or pressure drop across the airway in the first direction will generally be caused by patient inhalation.

In one embodiment the covering means is preferably in biased contact with the dose or container retaining the dose. Alternatively the covering means senses airflow through and/or pressure drop across the airway and responds thereto. Thus the covering means responds to airflow through and/or pressure drop across the airway in a first direction by opening.

The means for sensing the airflow though and/or pressure change across the airway and/or the means of responding thereto (i.e. opening said covering means and/or covering the dose more effectively) may incorporate electronic

means. Alternatively it may incorporate mechanical or electromechanical means.

When airflow through and/or pressure drop across the airway is in a second direction the covering means preferably responds by more effectively protecting the dose. For example it may more effectively protect the dose by being urged into closer contact with the dose or container retaining the dose.

The airflow through and/or pressure change in the second direction may generally be caused by the patient exhaling into the device.

The covering means may comprise one or more poppet valves, diaphragm valves, rotary valves, reciprocating valves, sealing flaps or a combination thereof.

There are various ways in which a dose can be metered. In one manner the metering occurs during the manufacturing process of the device ("pre-metered") and the metered dose is retained or located in discrete units. Alternatively the device contains a reservoir containing medicament and the dose is metered in use.

Metering may be based on volume of medicament or surface area.

For metering based on volume the dose may be metered in use or pre-metered into a container of the required volume. More specifically the container may be a pocket wherein the dose is retained after it has been metered. The pocket may also form a throughhole during operation of the device.

For metering based on surface area the dose may be retained on a tape. The covering means may then sit directly on the said dose.

In the dose protector the dose or container retaining the dose may have a surrounding rim. The rim around the dose, container retaining the dose or pocket is not specifically to retain the dose but preferably acts to create a better contact with the said covering means.

Especially preferred is a dose protector for use in an inhaler comprising a housing defining an airway; a pocket suitable for containing a dose of medicament; and at least one sealing flap in biased contact with said pocket and providing a cover for the pocket; wherein the contact between the at least one sealing flap and the pocket is broken by airflow through the airway in a first direction but not in a second opposite direction

Preferably, the sealing flap is spaced away from the pocket by the airflow from the pocket once the contact with the pocket is broken.

A further embodiment of the invention is a dose protector additionally comprising a closure mechanism wherein the at least one sealing flap is held in contact with the pocket by a closure means which prevents the contact between the at least one sealing flap and the pocket being broken by airflow through the airway in any direction. This can create a seal as the closure mechanism may correspond to and complement the shape of the rim. This provides an additional safety feature, decreasing the risk that a child could inhale the medicament accidentally. The movement of the closure mechanism could potentially be combined with the opening of the air inlet. The closure means applies a constant direct pressure on to the sealing flap thereby providing a seal with a long shelf life.

Preferably the pocket has a surrounding rim, which forms the contact point between the pocket and the sealing flap thereby providing a low contact area between the flap and the pocket.

Preferably the sealing flap is made of a flexible, resilient material with a memory, preferably a 3 year memory more preferably a greater than 3 year memory, i.e. the sealing flap stays resilient, biased against the pocket and flexible.

Preferably the sealing flap vibrates in the airflow once the contact with the pocket is broken. This has the effect of increasing the fine particle mass. Features which may influence the ability of the sealing flap are the flexibility of the material, preferably the sealing flap is made of highly flexible material for example a thermoset rubber, to allow the vibration to occur as the pressure changes in the device; the resilience of the sealing flap, if the resilience is too high the sealing flap may not open, if too low the sealing flap may not close therefore vibrations would not occur.

Preferably the sealing flap is of equivalent or slightly reduced width relative to the distance between the inside walls of the housing at the base of the walls of the housing where the sealing flap is in contact with the pocket. Preferably the distance between the inside walls of the housing increases as the distance away from the pocket increases preventing the sealing flap being hampered in its movement as it vibrates.

It will be appreciated that the vibrations of the sealing flap can be affected by the length of the sealing flap and its anchor position on the housing relative to the position of the pocket. The height of the airway may also effect the vibration of the sealing flap by influencing the curve of the sealing flap. The curve of the

sealing flap can be affected by having a locally thinned area on the sealing flap which acts as a hinge, instead of or as well as being made of a highly flexible material.

The covering means is preferably spaced away from the dose or container retaining the dose to coincide with the airflow through and/or pressure drop across the airway once the contact with the dose or container retaining the dose is broken.

In alternative embodiments of the invention the covering means may vibrate in the airflow through and/or pressure drop across the airway in the first direction.

The housing preferably contains a valve flap such that when the airflow is in a second opposite direction, the airflow exits the housing by means of the valve flap. This arrangement allows the airflow to escape from the housing, to prevent build up of pressure.

The said covering means preferably protects the dose from the patient exhaling into the device, moisture contamination, particulate contamination, loss of the dose (e.g. in the device) or a combination thereof.

Preferably the dose protector additionally comprises a fixed seal. This provides a further means by which to prevent loss of drug that can occur in transportation. It also can aid in reducing moisture contamination of the medicament during storage and transportation of the device. This seal (e.g. a pocket seal) will need to be removed before the patient uses the device, but protection of the dose after removal of the pocket seal will still be maintained by the covering means (e.g. sealing flap).

Another aspect of the invention is a dose protector in combination with a dose of medicament.

A second aspect of the invention is an inhaler comprising a body, a mouthpiece and a dose protector according to the invention.

Preferably the dose protector is for use in a dry powder inhaler. For example it may be a reservoir multidose dry powder inhaler, a pre-metered multidose dry powder inhaler or a unit dose dry powder inhaler.

Preferably in the inhaler the dose protector comprises at least one sealing flap in biased contact with a pocket, suitable for containing a dose of medicament, providing a cover for the pocket, the contact between the at least one sealing flap and the pocket being broken by airflow towards the mouthpiece.

Even more preferably the dose protector comprises least one sealing flap in biased contact with a pocket, suitable for containing a dose of medicament, providing a cover for the pocket, the contact between the at least one sealing flap and the pocket not being broken by airflow from the mouthpiece through the body.

Another aspect of the invention is an inhaler in combination with at least one dose of medicament.

Another aspect of the invention is the use of an inhaler for the administration of medicament.

Preferred embodiments of the inhalation device according to the present invention will now be described with reference to the accompanying drawings in which:

Fig. 1a is a sectional side view of a dose protector according to the present invention wherein the sealing flap is at rest.

Fig. 1b is a sectional side view of a dose protector according to the present invention wherein the airflow is in the direction to activate the sealing flap.

Fig. 2a is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the valve flap is at rest.

Fig. 2b is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the valve is open.

Fig. 2c is a sectional side view of a device as shown in Fig 1a and Fig 1b wherein the airflow is in the direction to activate the sealing flap.

Fig. 3a is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the pocket has geometry particularly suitable for a metered dose inhaler.

Fig. 3b is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the airflow is in the direction to activate the sealing flap.

Fig. 4a is a dose protector with closure mechanism in the closed position.

Fig. 4b is a dose protector with the closure mechanism in the open position.

Fig. 5 is a sectional side view of a device as shown in Fig 1a and Fig 1, with a pocket seal.

Fig. 6 is a sectional side view of a unit dose powder inhaler having a dose protector as shown in Fig 1a and Fig 1b, where the sealing flap is at rest.

Fig. 7 is a perspective view of a unit dose inhaler having a dose protector shown in Fig 1a and Fig1b at rest.

Fig. 8 is a perspective view of a moulding for a unit dose inhaler similar to that shown in Fig. 6.

Fig 9 is a different perspective view of a unit dose inhaler similar to that shown in Fig. 6

Figures 1a and 1b show a first dose protector comprising a sealing flap 10 and a pocket 20 suitable for containing a dose of medicament. The sealing flap 10 is resiliently biased into contact with the edge of the pocket 30 to reduce moisture contamination and loss of medicament during transportation. The sealing flap is fixedly attached to the body of the housing 40. When air flows towards the sealing flap as shown in Fig. 1b, such airflow being created by inhalation by the patient, the contact between flap 10 and the edge of the pocket 30 will break, and medicament is entrained in the airflow.

The sealing flap can vibrate to increase the fine particle mass of the medicament.

Fig. 1a shows that when the air flows towards the sealing flap 10 in the direction shown, the contact between the sealing flap 10 and the edge of the pocket 30 is

not broken, thereby maintaining the protection of the dose from moisture and particulate contamination. Such airflow would usually be created by exhalation.

Figures 2a, 2b and 2c show a second aspect of the invention having a hole 150 in the housing 140 so when the airflow is due to exhalation by the patient the valve flap 160 opens to let the moist air out. However when the airflow is in the opposite direction the contact between the sealing flap 110 and the edge of the pocket 130 is broken.

Figures 3a and 3b show a further dose protector according to the invention having a sealing flap 210 and a pocket 220 having geometry particularly suitable for a metered dose inhaler.

Figures 4a and 4b show the closure mechanism in an open and closed position. The locking means having slidable movement relative to the pocket where in the closed position the legs 380 sit over the edge of the pocket 330 trapping the sealing flap 310 between the legs and the edge of the pocket 330 preventing movement of the sealing flap 310. To open the device, the closure mechanism is slid relative to the pocket so that the legs 380 are not over the rim of the pocket and the sealing flap is not trapped, but free to move when airflow is in the correct direction.

Fig. 5 shows a dose protector according to the invention additionally having a pocket seal 490, which may be laminated, of foil or plastics material, which is removed to ready the device for use by the patient.

Fig. 6 shows a unit dose powder inhaler having a body 506 a mouthpiece 505 air inlet holes 507 a sealing flap 510 and a pocket 520. When the patient inhales through the mouthpiece 505 air flows into the device through the air inlet

holes 507 and the contact between the sealing flap 510 and the pocket 520 is broken. The medicament present in the pocket 520 is entrained in the airflow and carried through the device to be administered to the patient.

Fig 7 shows a unit dose inhaler wherein pocket 720 containing medicament is covered by sealing flap 710.

Fig 8 shows a one-piece moulding for a unit dose powder inhaler similar to that illustrated in Fig. 6 wherein 820 is the pocket and 810 is a sealing flap which bends into position when one half of the moulding is folded over and closed to form the finished device.

Mouldings as shown in Fig. 8 may be formed in arrays which allows for convenient filling of the pockets with medicament in an automated process.

Fig. 9 shows a unit dose inhaler with a pocket containing medicament 920 and a flexible resilient sealing flap 910 located fixedly through a tight fitting slot 970 in the top of the device. The material of the sealing flap is thinned at the slot to improve its positioning.

Throughout the specification and the claims which follow, unless the context requires otherwise, the word 'comprise', and variations such as 'comprises' and 'comprising', will be understood to imply the inclusion of a stated integer or step or group of integers but not to the exclusion of any other integer or step or group of integers or steps.

CLAIMS

1. A dose protector for use in an inhaler comprising a housing defining an airway; a dose of medicament optionally retained in a dose container; and covering means characterised in that said means is in biased contact with said dose or container retaining the dose and only opens in response to airflow though and/or pressure drop across the airway in a first direction but not in a second, opposite direction.

2. A dose protector as claimed in claim 1 wherein the covering means is only open in the presence of airflow through and/or pressure drop across the airway in a first direction after which it returns to its resting position.

3. A dose protector as claimed in claim 1 or claim 2 wherein the airflow through and/or pressure drop across the airway is caused by patient inhalation.

4. A dose protector as claimed in claims 1 to 3 wherein the said covering means senses airflow through and/or pressure across drop the airway and responds thereto.

5. A dose protector as claimed in claim 4 incorporating electronic means for sensing airflow through and/or pressure drop across the airway and/or means of responding thereto.

6. A dose protector as claimed in any preceding claim wherein the covering means responds by covering the dose more effectively when the airflow through and/or pressure drop across the airway is in a second direction.

7. A dose protector as claimed in claim 6 wherein airflow through and/or pressure drop across the airway in a second direction is caused by the patient exhaling.

8. A dose protector as claimed in claims 1 to 7 where the covering means comprises one or more poppet valves, diaphragm valves, rotary valves, reciprocating valves, sealing flaps or a combination thereof.

9. A dose protector as claimed in any one of claims 1 to 8 wherein the dose is metered by volume of medicament or surface area.

10. A dose protector as claimed in claim 9 wherein the dose is metered by volume into a container.

11. A dose protector as claimed in claim 10 wherein the said container is a pocket.

12. A dose protector as claimed in any preceding claim wherein the dose or container retaining the dose has a surrounding rim.

13. A dose protector for use in an inhaler comprising a housing defining an airway; a pocket suitable for containing a dose of medicament; and characterised in that it comprises at least one sealing flap in biased contact with said pocket and providing a cover for the pocket; wherein the contact between the at least one sealing flap and the pocket is broken by airflow through the airway in a first direction but not in a second opposite direction.

14. A dose protector as claimed in claim 13 wherein the sealing flap is spaced away from the pocket by the airflow once contact with the pocket is broken.

15. A dose protector as claimed in claim 13 or claim 14 additionally comprising a closure mechanism wherein the at least one sealing flap is held in contact with the pocket by a closure means which prevents the contact between the at least one sealing flap and the pocket being broken by airflow through the airway in any direction.

16. A dose protector as claimed in claim 15 wherein the pocket has a surrounding rim.

17. A dose protector as claimed in any one of claims 13 to 16 wherein the said sealing flap vibrates in the airflow once the contact with the pocket is broken.

18. A dose protector as claimed in any one of claims 13 to 17 wherein the sealing flap is made of thermoset rubber.

19. A dose protector as claimed in any one of claims 13 to 18 wherein the sealing flap is of equivalent or slightly reduced width relative to the distance between the inside walls of the housing at the base of the walls of the housing where the sealing flap is in contact with the pocket.

20. A dose protector as claimed in claim 19 wherein the distance between the inside walls of the housing increases as the distance away from the pocket increases.

21. A dose protector as claimed in claims 1 to 12 wherein the said covering means is spaced away from the dose or container retaining a dose to coincide with the airflow through and/or pressure drop across in the first direction once the contact with the dose or container retaining the dose is broken.

22. A dose protector as claimed in any one of claims 1 to 21 wherein the covering means vibrates in the airflow through and/or pressure drop across the airway in the first direction.

23. A dose container as claimed in claims 1 to 22 wherein the housing contains a valve flap such that when the airflow is in a second opposite direction, the airflow exits the housing by means of the valve flap.

24. A dose protector as claimed in any preceding claim wherein the said covering means protects the dose from the patient exhaling into the device, moisture contamination, particulate contamination and loss of the dose or a combination thereof.

25. A dose protector as claimed in any preceding claim additionally comprising a fixed seal.

26. A dose protector as claimed in any one of claims 1 to 25, in combination with a dose of medicament.

27. An inhaler comprising a body, a mouthpiece, and a dose protector as claimed in any preceding claim.

28. An inhaler as claimed in claim 27 wherein the said inhaler is a dry powder inhaler.

29. An inhaler as claimed in claim 26 or claim 27 in combination with at least one dose of a medicament.

30. Use of an inhaler as claimed in any one of claims 27 to 29 for the administration of medicament.

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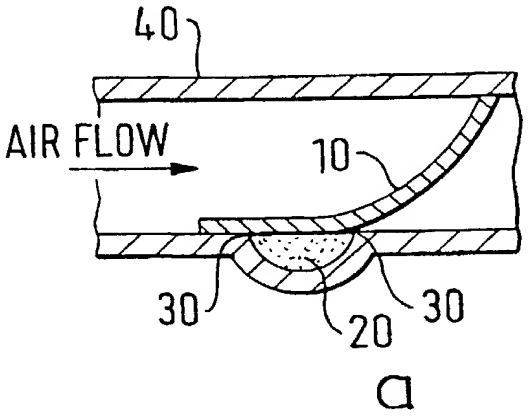
(57) Abstract

A dose protector for use in an inhaler comprising a housing (40) defining an airway; a dose of medicament optionally retained in a dose container (20, 30); and covering means (10) for said dose wherein covering means (10) for the dose only opens in response to airflow through and/or pressure drop across the airway in a first direction but not in a second, opposite direction.



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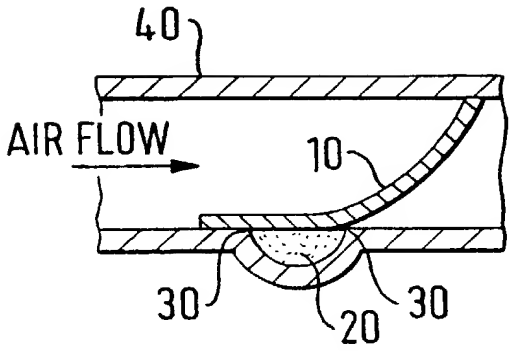

FIG. 1a

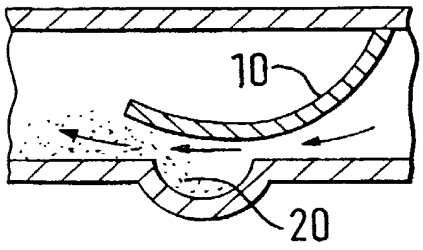

FIG. 1b

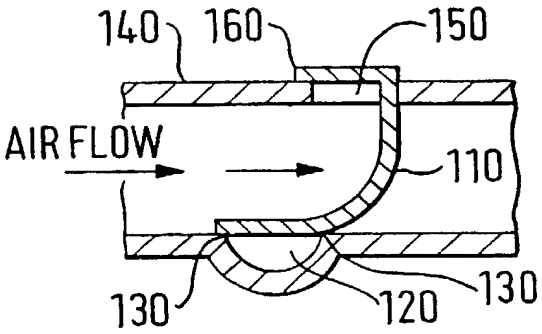

FIG. 2a

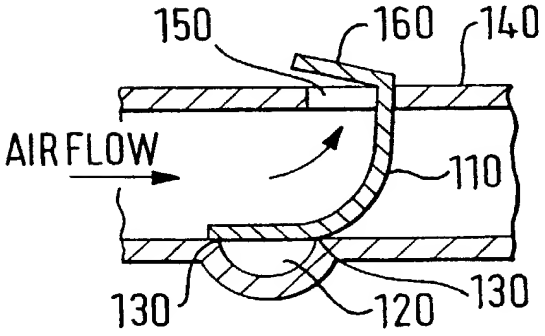

FIG. 2b

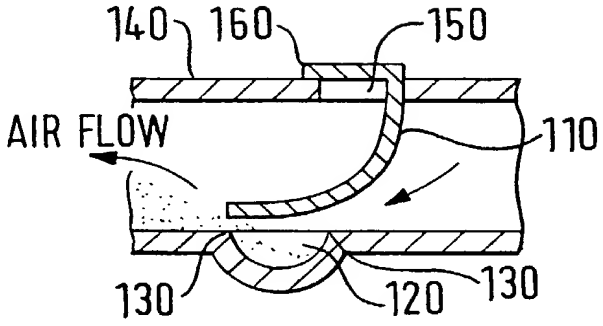

FIG. 2c

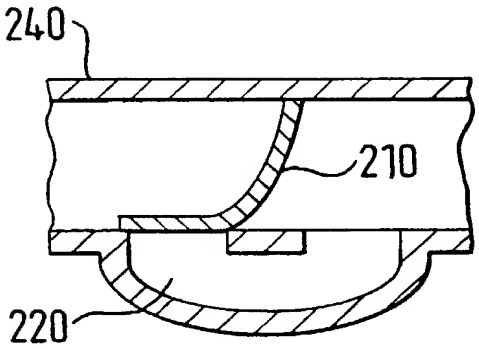

FIG. 3a

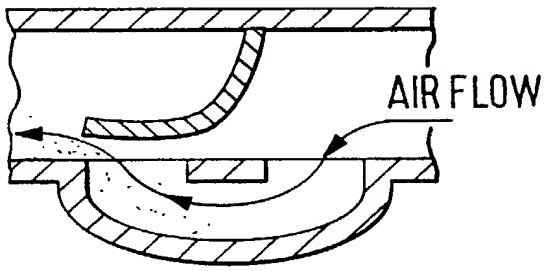

FIG. 3b

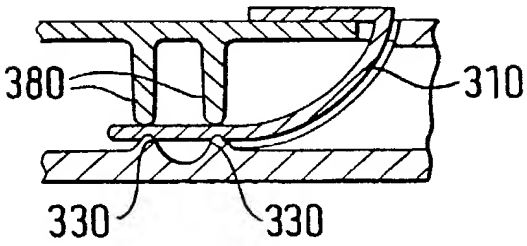

FIG. 4a

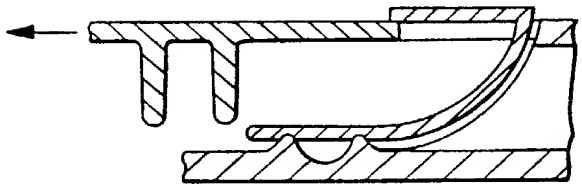

FIG. 4b

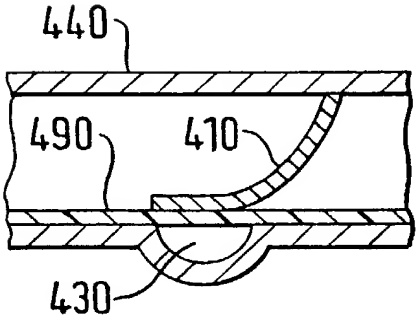

FIG. 5

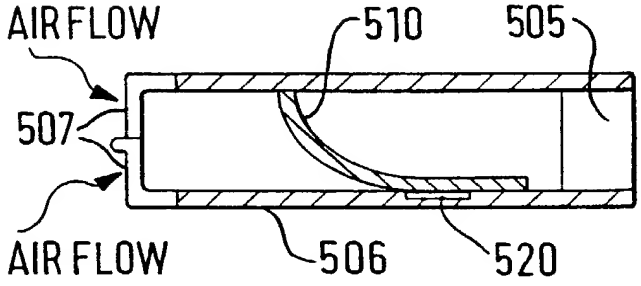

FIG. 6

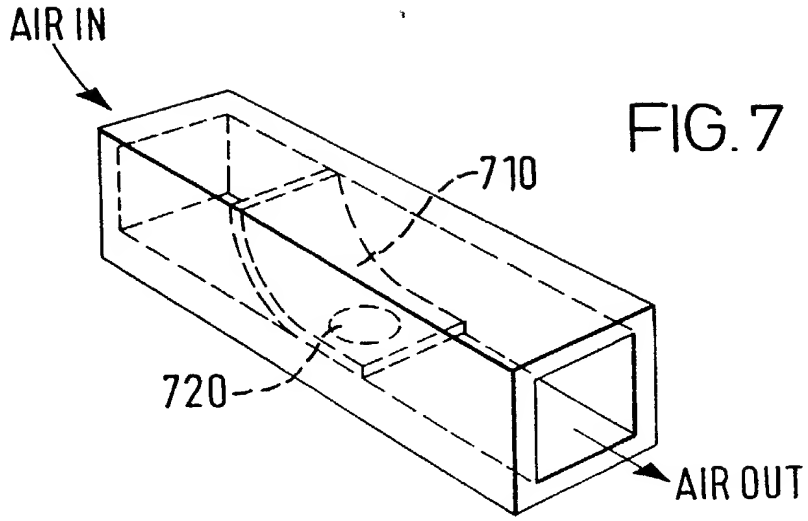

FIG. 7

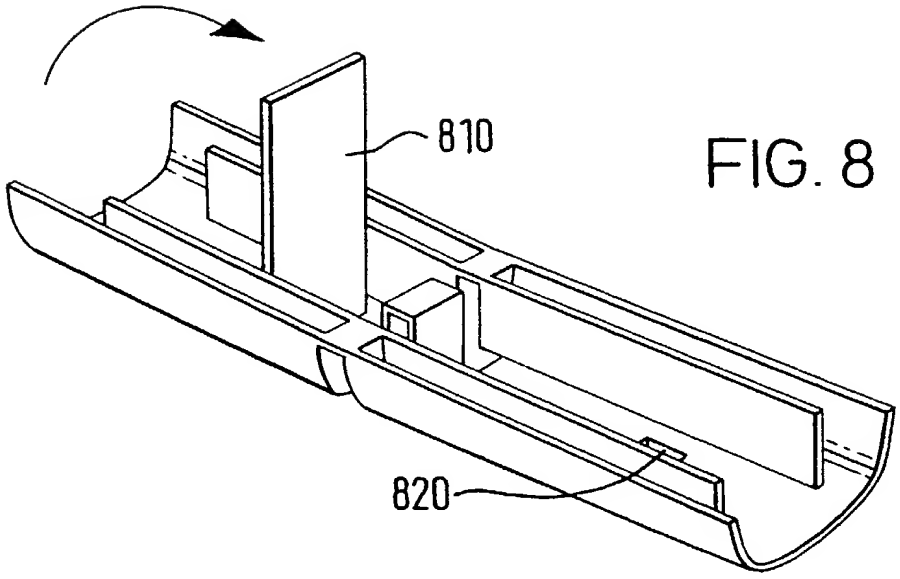

FIG. 8

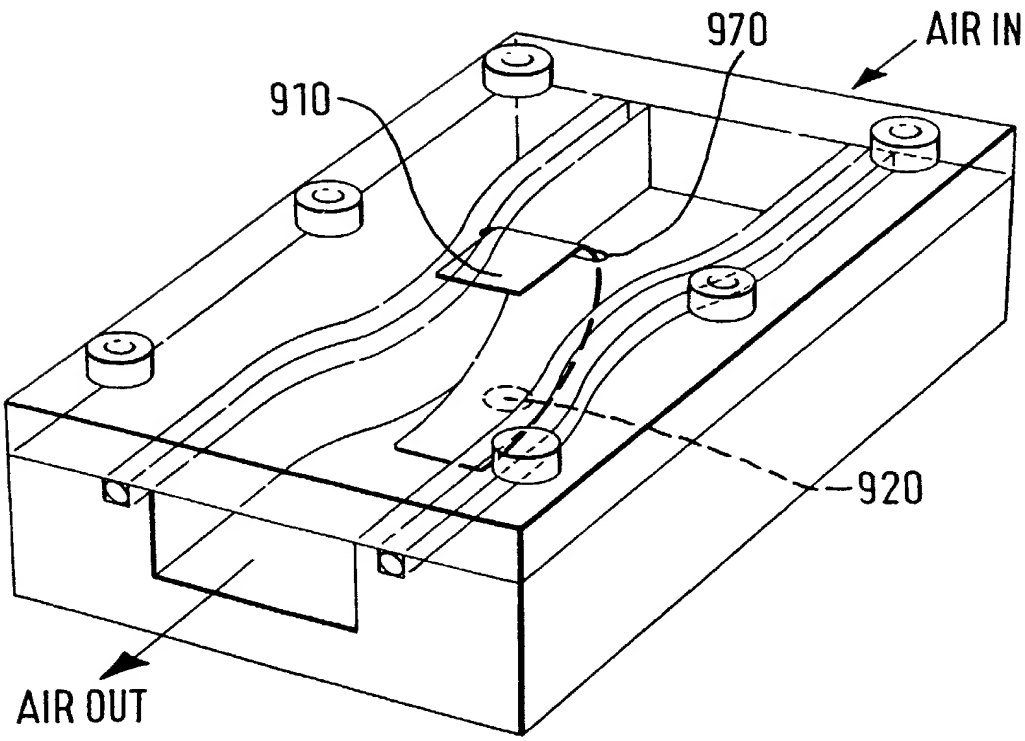

FIG. 9

DECLARATION FOR "371" APPLICATION

COMBINED DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION WITH POWER OF ATTORNEY

( ) Declaration submitted with initial filing or

( )Declaration submitted after initial filing (surcharge required 37CFR1.16(e))

ATTORNEY'S DOCKET
PG3619USW

First Names Inventor:
Michael Birsha DAVIES

Complete if known:
App No.:
09/914,999

Filing Date

Group Art Unit:

As below named inventor. I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Dose Protector for Inhalation Device

the specification of which (check only one item below):

[ ]is attached hereto.
OR
[x] was filed on **10 March 2000** as United States application Serial No. _____ or **PCT** International

Application Number **PCT/GB00/00919** filed and was amended on (MM/DD/YYYY) _____(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35, U.S.C. §119 (a)-(d) or §365(b) of any foreign applications(s) for patent or inventor's certificate or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

Prior Foreign Application Number (s)	Country	Foreign Filing Date (MM/DD/YYYY))	PRIORITY CLAIMED
1 9905538.6	GB	03/10/1999 (March 10, 1999)	X
2.			
3.			

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date (MM/DD/YYYY)	
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DECLARATION FOR "371" APPLICATION

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ATTORNEY'S DOCKET NUMBER: PG3619USW

I hereby claim the benefit under 35, U.S.C. §120 of any United States application or §365(c) of any PCT international application designating the United States of America that is listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application.

PRIOR U.S. PARENT APPLICATION or PCT PARENT APPLICATION

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	STATUS (Check one) PATENTED	PENDING	ABANDONED

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith. (List name and registration number)

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2	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME/INITIAL
	INVENTOR'S SIGNATURE	Signature		Date
0	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
2	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
2	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME/INITIAL
	INVENTOR'S SIGNATURE	Signature		Date:
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